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LILLING,H	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. ~~41~~ 40

Application Number: 08/458,019
Filing Date: June 01, 1995
Appellant(s): Johnson et al

Attorney George S. Jones
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed August 23, 2000.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

This is in response to appellant's brief on appeal filed August 23, 2000.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

5,356,810	FLENO ET AL	October 18, 1994

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

(a) Claims 25-34 stand rejected under 35 U.S.C. 112 first paragraph for **lack of the requested required Deposits** commensurate in scope with the claimed inventions in accordance with PTO rules requiring Deposits;

(b) Claims 25-34 stand rejected for **the written description** requirement under 35 U.S.C. 112 first paragraph. Applicants did not have possession of the broad claimed generic invention at the time the application was filed.

(c) Claims 25-34 stand rejected under 35 U.S.C. first paragraph with respect to the enabling description to make and use the invention commensurate in scope with the claimed inventions in accordance with e.g. In re Wands 858 F.2d 731, 8 USPQ2d 1400 (fed Cir 19880 and Foers vs Sugano, 25 USPQ2d. 1601;

and

(d) Claims 25-34 stand rejected under the Judicially created doctrine of obviousness-type double patenting over claims 5,356,810 in accordance with MPEP 800-13 rev. 1 September 1995 Chart IIB-conflicting claims between **APPLICATION AND A PATENT**;

The above rejections, Claims 25-34 stand rejected as stated in the prior Office actions dated July 29, 1998 and December 02, 1998 in accordance with the Final Rejection of September 23, 1999. The rejection is set forth in prior Office action

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Paper No 34 as reproduced:

1. Receipt is acknowledged of the request for reconsideration filed April 02, 1998.
2. Claims 25-34 remain present in the instant application.
   Claims 1-24 were previously canceled.
3. The request for reconsideration has been noted but all of the prior rejections as stated in the prior Office action dated July 29, 1998 and December 02, 1998 have been maintained.
   This Examiner has to abide by the rules of the MPEP which indicates that the current rejections are appropriate. This Examiner wishes Applicant the best in the pursuit of overturning the rejections by a higher Authority.

As indicated in the previous Office action:

'Applicant is entitled to appeal the above rejections to the Patent Board of Appeals and Interference.'
HOWEVER, 'This Examiner will probably maintain the above rejections for the broad claimed genus especially the written description rejections with the approval of the Supervisor and the Special Program Examiner.' DEPOSITS ARE REQUIRED FOR THESE MUTANTS due to the unpredictability of the claimed subject matter in accordance with the

decisions cited in the previous Office action.

4. No claim is allowed.

5. THIS ACTION IS MADE FINAL.....

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Art Unit 1651
December 02, 1998

July 28, 1998 as reproduced:

15. The **FINALITY** has been **WITHDRAWN.**

16. Receipt is acknowledged of the request for reconsideration filed July 10, 1998.

17. Claims 25-34 remain present in the instant application. Claims 1-24 were previously canceled.

18. The rejection over the prior art has been withdrawn since the effective date for the prior art is not the priority date April 15,1987 but November 12, 1989 and the earliest publication date is for WO8808025 published October 20, 1988.19.The rejection as noted in the last Office action as noted in paragraph 17 has been maintained which recites:

> Claims 25-34 **stand** rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 5,356,810. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are within the scope of the claimed subject matter.
>
> The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).
>
> A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign November 25, 1997 November 25, 1997 the assignee must fully comply with 37 CFR 3.73(b).

It is noted that there is one inventor in common with the patent and the application, see MPEP 800-13, rev 1 Sept 1995, chart IIB..-conflicting claims between **APPLICATION AND A PATENT**.

The arguments submitted have been deemed not to be persuasive since the filing date is not an issue in a Double Patenting of the Obvious-type.

According to the chart indicated above, this Examiner cannot set-up an interference to settle the conflicting claims unless there is an error in the Manual pertaining to this flow sheet.

The arguments submitted by Applicant on April 01, 1998 have been considered but this Examiner is bound by the procedures outlined above that is in the MPEP. There is no leeway for this Examiner to change the procedure or to disregard the above action. The instant claims and the patented claims are not drawn to the same invention but is within the guidelines of double patenting of the obviousness type. The request that "...the only possible course of action the Examiner can pursue is to withdraw the rejection." cannot be possible but Applicant can request the Board of Appeals to overcome the rejection which is based on an impossible position placed on Applicant set-up by the MPEP chart in which one of the inventors is in common with two applications in which the applications are not commonly owned.
The arguments have been found not to be persuasive since Applicant has argued a different point and not the one as noted by the Examiner---that is, only one of

the inventors and that the chart indicated the appropriate rejection.

The rejection has to be maintained based on the guidelines of the M.P.E.P. which may be in error but a higher authority must overturn the above rejection based on ※double patenting of the obviousness type※ as required by the MPEP chart.

20. Claims 25-34 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention as enabling for the claimed microorganisms in accordance with the U.S. Rules of Deposits.

It is apparent that the additional strains are required to practice the claimed invention(s) as recited in the claims. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of these additional strains. See 37 C. F. R. 1.802.

If a deposit has not been supplied or made under the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements, See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is

in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

a) during the pendency of the application, access to the deposit will be afforded to one determined by the Commissioner to be entitled thereto;

b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent;

c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

d) a viability statement in accordance with the provisions of 37 CFR 1.807;

and

e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 CFR 1.809(d) should be added to the specification, See 37 CFR 1.803-37 CFR 1.809 for additional explanations of these requirements.

The prior arguments are not persuasive for one of ordinary skill in the art to reproduce all of the mutants encompassed by the claimed inventions since the claims are drawn to products and not processes.

Will accept product by process claims to claim all additional strains not deposited.

This rejection has been maintained in view of the Office requirement for deposits that are commensurate with the claimed language as noted above. The arguments have been deemed not to be persuasive to withdraw the rejections.

21. Claims 25-34 stand rejected under 35 U.S.C. § 112, first paragraph as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make.

The following decisions which may be pertinent to the claimed language which may be extremely broad for the microorganism, see: In re Fisher, 168 USPQ 18, 24 (June 11 1970)

Such improvements, while unobvious from his teachings, are still within his contribution, since the improvement was made possible by his work. It is equally apparent, however, that he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. 112. that paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.....In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.
In view of the broad claimed language, the above statement:

It is equally apparent, however, that he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. 112. that paragraph requires that the scope of the claims must bear a

reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art..

Further decision, see Fiers v. Sugano 25 USPQ2d. 1601. The decision clearly states:

"Claiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived." This above statement is complete concordance with the above decision to In re Fischer. Applicant is absolutely not entitled to the broad claimed language for the "mutant Phaffia" which "requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity." Also, stated "We thus determined that, irrespective of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance, requires a definite of that substance other than by its functional utility." Applicant does not teach in the instant specification any and all mutant strains to produce pigments at a certain level but only specific mutant strains.

The arguments that the scope of the claims are enabling in view of the alleged screening methods to obtain astaxanthin mutants is not fully persuasive. As indicated above, if the claims are drawn to product by processes, the claims would be considered favorably for allowance. The scope of the claims are broader than the enabling and the rejection of the broad claimed language is in accordance with the above decision of In re Fisher Fischer and Fiers v. Sugano..

The Claims stand rejected under 35 U.S.C. § 112, first paragraph, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same with respect to

the claimed language which is considered to be extremely broad for the microorganism per se - See In re Wands 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404(fed Cir 1988) whereby it was noted the factors to be considered have been summarized as

the quantity of experimentation necessary,
the amount of direction or guidance presented,
the presence or absence of working examples,
the nature of the invention,
the state of the prior art,
the relative skill of those in that art,
the predictability or unpredictability of the art
and

the breadth of the claims

which factors in this present case presents a case of "undue experimentation" to make and practice the claimed specific microorganisms in view of the claimed language which is considered to be extremely broad.

The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness in view of the above factors and the quantity of experimentation necessary required in light of the amount of direction or guidance submitted in this instant application to isolate and practice the instant inventions without undue experimentation.

22. Claims 25-34 **are rejected under 35 U.S.C. 112, first paragraph, as**

containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification lacks adequate written description for the claimed inventions in view of the following points in accordance with the written description requirements of 35 U.S.C. 112:

The description must clearly allow persons of ordinary skill in the art to recognize what is claimed. Thus, an applicant must comply with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107

F.3d at 1572, 41 USPQ2d at 1966. An adequate written description of the enzyme , "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601,1606 (Fed. Cir. 1993). Accordingly, an adequate written description of a transformed microorganism requires more than a mere statement that it is part of the invention and reference to a potential method for preparing it; what is required is a description of the transformed microorganism itself.

A written description of a microorganism invention involving a genus, like a description of makeup of the claimed subject matter sufficient to distinguish it from other materials see Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284- 85 (CCPA 1973).

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

The lack of specificity for the broad claimed language for the products per se which are described as mutant Phaffia rhodozyma microorganisms which are capable of producing astaxanthin does not meet the description requirement which requires a precise definition of the microorganisms .

Applicant is required to be enabling for the broad scope since the record does not support the broad claimed language.

23. No claim is allowed.

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REJECTED ISSUES:

(a) : REJECTION BASED ON DEPOSIT REQUIREMENTS

The rejection of Claims 25-34 under 35 U.S.C. 112 first paragraph stands as stated above for **lack of the required Deposits** commensurate in scope with the claimed inventions in accordance with PTO rules requiring Deposits. Appellants have only submitted deposits which were in full compliance with the U.S. Deposit Rules for the mutants commensurate in scope with the **claims allowed** by this Examiner in U.S. Patent Number 5,356,809. The instant claims are drawn to broader claimed subject matter for the **mutant** strains of Phaffia rhodozyma which additional strains have not been deposited nor described how to make and use these additional strains commensurate in scope with the claimed subject matter. Thus, the reasonable request for at least one or more additional mutant strains commensurate in scope with the claimed subject matter are required as noted in the above paragraph 20 of the Office action dated July 28, 1998.

Appellants are not in compliance with the requirements of the Depository Rules in the U.S. since one of ordinary skill in the art would not have been able to make and prepare the mutant strains based on the instant disclosure commensurate in scope with the broad claimed inventions prepared by other methods, see US-PAT-NO: 5356810:

> "1.An isolated pure culture of a strain of Phaffia rhodozyma which when grown under conditions comprising an oxygen transfer rate of at least 30 mmoles/1/hour on YM medium at 20.degree.-22.degree. C. for 5 days in 500 ml shake flasks with two baffles containing 50 ml of the medium and subjected to orbital shaking at 150 rpm, produces astaxanthin in an amount of at least 600 .mu.g per g Phaffia rhodozyma dry matter, as determined by HPLC analysis, wherein said strain is Phaffia rhodozyma deposited under accession No. 224-87 CBS, accession No. 225-87 CBS, or accession No. 215-88 CBS, or a mutant thereof which retains the astaxanthin-producing capability."

or/and **US-PAT-NO: 5466599**:

Whereby the patent states:

> "Phaffia rhodozyma strains are described which produce greater than 3,000 ppm astaxanthin based on dry yeast solids when cultivated in a volume of nutrient medium of at least about 1,500 liters and containing in excess of 4 percent, preferably in excess of 6 percent, dry yeast solids. These and other strains are cultivated by an improved fermentation method comprising extending the maturation phase of the fermentation by one or more various **techniques including exposing the yeast cells to a low-intensity light**, slow feeding the cells with a rapidly metabolized energy source, e.g. glucose, and replacing the rapidly metabolized energy source with a slowly metabolized energy source, e.g. glycerol."

Appellant is required to submit a reasonable number of species that would be commensurate in scope with the term "mutant" since the specification lacks the requirement of **how to make** the mutant strains in accordance with the Deposit Rules:

> As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of these additional strains.

Appellants do not satisfy the above requirement for the Deposit Rules.

(b): REJECTION BASED ON WRITTEN DESCRIPTION REQUIREMENT

Claims 25-34 stand rejected for the written description requirements under 35 U.S.C. 112 first paragraph .The following is a quotation of the **first paragraph of 35 U.S.C. 112**:

> The specification shall contain a **written description of the invention**, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the

same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification lacked adequate written description for the claimed inventions to inform a skilled artisan that applicant was in possession of the claimed invention at the time the application was filed, see **Eli Lilly, 119 F. 3d** 1559, 43 USPQ2d 1398 (Fed. Cir 1997).

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

The lack of specificity for the broad claimed language for the **products per se** which are described as "**mutant**" strains of Phaffia rhodozyma microorganisms which are **capable of** producing astaxanthin do not meet the description requirement which requires a precise definition of the microorganisms.

Appellants are required to be enabling for the broad scope since the record does not support the broad claimed language for the selected "mutant" in the expression "mutant Phaffia rhodozyma"in the absence of (a) antibiotic, (b) cytochrome B inhibitor, or (c) terpenoid synthetic pathway inhibitor which are required "in the protocol" selection, see page 17, third line from bottom of the page. Appellant has already been granted a patent based on this protocol parent application, see **U.S. Patent 5,356,809**:

> 1. Phaffia strain IGI887J0.
> 2. A mutant strain of Phaffia IGI887J0 of claim 1 which produces at least 700 .mu.g of astaxanthin per gram dry weight of Phaffia per six day culture period in YM medium, wherein said astaxanthin is determined by measuring the absorbance at 474 nanometers of a

petroleum ether extract of Phaffia using a 1% (w/v) extinction coefficient in a 1 centimeter cuvette of 2100.

3. Phaffia strain IGI887J2.

4. A mutant strain of Phaffia IGI887J2 of claim 3 which produces at least 700 .mu.g of astaxanthin per gram dry weight of Phaffia per six day culture period in YM medium, wherein said astaxanthin is determined by measuring the absorbance at 474 nanometers of a petroleum ether extract of Phaffia using a 1% (w/v) extinction coefficient in a 1 centimeter cuvette of 2100.

and in **U.S. Patent 5,182,208:**

1. A process for the production of a yeast having a enhanced astaxanthin content, comprising culturing a microorganism of genus Phaffia in a nutrient medium containing at least one of (i) an antibiotic selected from the group consisting of antimycin, tunicamycin, and nystatin, and (ii) mevalonic acid lactone.

.....

4. A process as in claim 1, wherein said culturing in a nutrient medium containing at least one of (i) an antibiotic, and (ii) mevalonic acid lactone results in morphological selection of a microorganism of genus Phaffia exhibiting enhanced pigmentation, and wherein said microorganism of genus Phaffia is subjected to mutagenesis either before, after, or before and after said morphological selection.

5. A process as in claim 1, employing as said yeast P. rhodozyma ATCC 24230 to ATCC 24202.

.....

12. A process for the production of a yeast having an enhanced astaxanthin content, comprising culturing a microorganism of genus Phaffia one or more times in a nutrient medium containing at least one of (i) an antibiotic selected from the group consisting of antimycin, tunicamycin, and nystatin, and (ii) mevalonic acid lactone, cultivating surviving microorganisms exhibiting enhanced pigmentation, harvesting the cultivated yeast, and extracting the astaxanthin.

13. **A process as in claim 12, further comprising subjecting said microorganism of genus Phaffia to at least one mutation either before or after one of said culturing(s) in said nutrient medium containing said at least one of (i) an antibiotic selected from the group consisting of antimycin, tunicamycin, and nystatin, and (ii) mevalonic acid lactone.**

14. A process for the production of a yeast having an enhanced astaxanthin content, comprising culturing a microorganism of genus Phaffia in a nutrient medium containing an inhibitor of electron transport which blocks

> the transfer of electrons from cytochrome b to c in a yeast of genus Phaffia.
> 15. A process as in claim 14, wherein said culturing in a nutrient medium containing a cytochrome B inhibitor results in morphological selection of a microorganism of genus Phaffia exhibiting enhanced pigmentation, and wherein said microorganism of genus Phaffia is subjected to mutagenesis either before, after, or before and after said morphological selection.
> 16. A process as in claim 14, employing as said yeast Phaffia rhodozyma ATCC 24230 or ATCC 24202.
> .....

This Examiner has already granted Appellants the broadest claims in accordance with written description and enabling disclosure commensurate in scope with the specification. Appellant was in full compliance in submitting the required microorganism(s) commensurate in scope with the allowed claims. Appellants are not in compliance with the instant claims with respect to the required microorganisms which have not been submitted due to the extremely broad claimed inventions which read on **any mutant** Phaffia rhodozyma microorganism whereby strains are prepared by another and materially different method as in e.g.,US-PAT-NO: 5,356,810:

> 1.An isolated pure culture of a strain of Phaffia rhodozyma which when grown under conditions comprising an oxygen transfer rate of at least 30 mmoles/1/hour on YM medium at 20.degree.-22.degree. C. for 5 days in 500 ml shake flasks with two baffles containing 50 ml of the medium and subjected to orbital shaking at 150 rpm, produces astaxanthin in an amount of at least 600 .mu.g per g Phaffia rhodozyma dry matter, as determined by HPLC analysis, wherein said strain is Phaffia rhodozyma deposited under accession No. 224-87 CBS, accession No. 225-87 CBS, or accession No. 215-88 CBS, or a mutant thereof which retains the astaxanthin-producing capability.

And in **US-PAT-NO 5,466,599**

Whereby the patent states:

> "Phaffia rhodozyma strains are described which produce greater than 3,000 ppm astaxanthin based on dry yeast solids when cultivated in a volume of

> nutrient medium of at least about 1,500 liters and containing in excess of 4 percent, preferably in excess of 6 percent, dry yeast solids. These and other strains are cultivated by an improved fermentation method comprising extending the maturation phase of the fermentation by one or more various **techniques including exposing the yeast cells to a low-intensity light**, slow feeding the cells with a rapidly metabolized energy source, e.g. glucose, and replacing the rapidly metabolized energy source with a slowly metabolized energy source, e.g. glycerol."

Appellants do not teach or disclose in the written description for one of ordinary skilled in the art to make and practice the instant inventions commensurate in scope with the claimed subject matter absent the required deposited strains commensurate in scope with the claimed inventions. The term "mutant" encompasses numerous different types of "mutants" for which deposits are required but Appellants have resisted to submit deposits based on the allegations that the present specification provides sufficient guidance in accordance with 35 U.S.C. 112, first paragraph. The arguments have been found not to be persuasive since Appellants have already been granted claims as broad as the written disclosure based on the deposited strains. There is absolutely no guidance how to make in the instant written description of additional mutant strains by any other method than the protocol as indicated on page 17 which processes requires selection of the mutants in the presence of (a) antibiotic, (b) cytochrome B inhibitor, or (c) terpenoid synthetic pathway inhibitor.

Whether a specification complies with the written description requirement of § 112, first paragraph, is a question of fact *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991); *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985). To fulfill the written description requirement, a specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that

"the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, the written description requirement is satisfied "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966. The written specification does not satisfy this requirement for the scope in sufficient detail having the required written description commensurate in scope with the claimed inventions and thus, Appellants did not have possession of the claimed invention at the time of filing the instant application.

Whether or not the disclosure provides an enabling disclosure, it **does not provide a written description of the desired microorganisms** which is necessary to provide a written description of the mutant microorganisms. The functional property is not itself a written description of that microorganism, "astaxanthin mutant", it conveys no distinguishing information concerning its identity as to the "mutant", just its functional property that produces astaxanthin. While the disclosure provides a process for obtaining an additional microorganisms with the claimed properties only by a specific protocol which limitation(s) is (are) not in the claims, there is no further information in the application pertaining to the desired organisms characteristics; in other words, it does not describe microorganisms having the desired functional property in general. Describing a method of finding a

suitable microorganism having the desired functional property, mutant producing astaxanthin, as in the example, does not necessarily describe the desired microorganism itself.

The Claims **stand** rejected under 35 U.S.C. § 112, first paragraph, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention with respect to the claimed language which is considered to be extremely broad for the microorganism and the enzymes per se - See **In re Wands** 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404(fed Cir 1988) whereby it was noted the factors to be considered have been summarized as

the quantity of experimentation necessary,

the amount of direction or guidance presented,

the presence or absence of working examples,

the nature of the invention,

the state of the prior art,

the relative skill of those in that art,

the predictability or unpredictability of the art

and

the breadth of the claims

which factors in this present case presents a case of "undue experimentation" to make and practice the claimed inventions which is considered to be extremely broad.

The determination of what constitutes undue experimentation in a given case requires the application of a **standard of reasonableness** in view of the above factors and the quantity of experimentation necessary required in light of the amount of direction or guidance submitted in this instant application to obtain additional microorganisms and practice the instant inventions without undue experimentation.

In addition, **the specification lacks adequate written description** for the claimed inventions in view of the following points in accordance with the written description requirements of 35 U.S.C. 112:

The description must clearly allow persons of ordinary skill in the art to recognize what is claimed. Thus, an applicant must comply with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966. An adequate written description of the microorganisms requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re

Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Claims remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The broad generic claim lacks sufficient description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing since the specification lacks a sufficient number of species which have been described by complete structure or identifying characteristics, thus the description requirement has not been satisfied, see **Eli Lilly, 119 F. 3d** 1559, 43 USPQ2d 1398 (Fed. Cir 1997) .

(c) REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH ENABLEMENT

The **enablement** requirement of 35 U.S.C., 112, first paragraph, requires that the patent specification enable those skilled in the art to make and use the full scope of the claimed invention without undue experimentation. The instant claims stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the protocol as noted on page 17 which requires (a) antibiotic, (b) cytochrome B inhibitor, or (c) terpenoid synthetic pathway inhibitor for the mutant selections , does not reasonably provide enablement to make and use the inventions for the full scope of the claimed inventions without undue experimentation . The specification does not reasonably provide enablement for mutants obtained by the methods as described in the above

paragraphs, as noted in US-PAT-NO: 5,356,810 and US-PAT-NO 5,466,599 without undue experimentation since the specification lacks suitable guidance to make and use these mutants.

The specification according to **In re Fisher,** 427 F. 2d 833, 839, 166 USPQ 18, 24 (CCPA 1970): Section 112 requires that the scope of the claims must bear a **reasonable correlation to scope of enablement** provided by the specification to persons of ordinary skill in the art.

In cases involving unpredictable factors, such as most chemical reactions and physiological activity as well as pertaining to microorganisms, the scope of the enablement varies inversely with degree of unpredictability of the factors involved. This unpredictability pertaining to microorganisms is supported by the U.S. Rules of Deposits which requires deposits of new microorganisms in Depositories. .

The instant claims are essentially of limitless breadth as it is implied by Appellants that so long as the specification provides one with the ability to make any particular embodiment which is encompassed by the material limitations of any mutant of Phaffia rhodozyma which produces at least 700 micrograms of astaxanthin, one can thereby practice those embodiments which meet the functional limitations. This argument is not entirely without merit. However, the issue here is the breadth or enablement of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. This 'make and test' position is inconsistent with the decisions in *In re Fisher*, 427 F.2d 833, 166 USPQ 18 (CCPA 1970), *Amgen v. Chugai Pharmaceuticals Co. Ltd.*, 13 USPQ2d, 1737 (1990), and *In re Wands*, 8 USPQ2d, 1400 (CAFC 1988). *In re Wands* stated that the factors to be considered in determining whether a

disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and, (8) the breadth of the claims.

Breadth alone is not the issue, however. *In re Fisher,* 427 F.2d 833, 166 USPQ 18 (CCPA 1970), held that

> "Inventor should be allowed to dominate future patentable inventions of others where those inventions were based in some way on his teachings, since such improvements while unobvious from his teachings, are still within his contribution, since improvement was made possible by his work; however, he must not be permitted to achieve this dominance by claims which are insufficiently supported and, hence, not in compliance with first paragraph of 35 U.S.C. 112; that paragraph requires that scope of claims must bear a reasonable correlation to scope of enablement provided by specification to persons of ordinary skill in the art; in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific law; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictability of factors involved."

Having established the breadth of the claims which are considered to be extremely broad for the expression "astaxanthin producing mutant Phaffia rhodozyma", *Wands* now requires that one consider the number of working examples presented in the instant specification. The instant specification only provides for numerous species of microorganism that can perform the desire production of astaxanthin producing mutants by **employing the protocol as taught on page 17** which are

supported by only those deposited mutants which products and processes by which Appellants have already been granted patents on those mutants, and absolutely no additional deposited strains commensurate in scope with the full claimed mutant .

The breadth of claims must be based upon the predictability of the claimed subject matter and not on some standard of trial and error. To argue that one can make material embodiments of the invention and then test for those that work in the manner disclosed or that the instant claims only encompass the working embodiments is judicially unsound. Unless one has a **reasonable expectation** that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are **more likely to work that not** without actually making and testing them then the instant application does not support the breadth of the claims. In the instant case, it is highly improbable that any astaxanthin mutant of a Phaffia rhodozyma microorganism will more likely than not perform in the manner disclosed other than that disclosed on page 17 by the instant protocol and the instant specification does not provide the guidance needed to find other microorganisms with the desired functional property with any reasonable expectation that such microorganisms will be found absent the disclosed protocol.

The factors which were considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. para 112 were ....adopted by this board in **Ex parte Forman**, 230 USPQ 546 (BPAI 1986). Among these factors are:

1) the nature of the invention,

2) the state of the prior art,

3) the predictability or lack thereof in the art,

4) the amount of direction or guidance present, and

5) the presence or absence of working examples.

In this particular case,

1) Nature of invention:

There is a reasonable likelihood that a satisfactory "mutant" would not be found having the required functional property of being capable producing more than 700 micrograms employing any other protocol based on the instant specification due to the unpredictability of microorganisms as supported by the Deposit Rules which require deposits for microorganisms.

2) State of Prior Art:

As disclosed by the present record, the prior art indicates that the production of astaxanthin by Phaffia rhodozyma microorganisms capable of producing astaxanthin was lower than 700 micrograms.

3) Predictability:

Appellant's invention concerns activity by mutant microorganisms. Because there is no evidence of record of analogous activity for producing amounts of astaxanthin higher than 700 micrograms by **similar mutants, the art is relatively unpredictable.**

4. Guidance:

The guidance is for only one particular protocol method of selecting " astaxanthin mutant " strains of Phaffia rhodozyma and there is no disclosure of any other protocol selection for obtaining the mutant strains. Even if there is any broad allegations or suggestions, the specification does not

describe any guidance by any **substantiating working examples** drawn to the mutant strains by any other protocol selection method.

5. Working examples:

Appellant has provided no working examples or experimental evidence regarding the effectiveness for obtaining mutant strains absent the protocol method taught on page 17 and in the examples. Though not controlling, the lack of working examples, is, nevertheless, a factor to be considered in a case involving **both physiological activity and an undeveloped art.** "

(11) Response to Argument

The arguments have been deemed not to be persuasive to withdraw the above rejections.

A. Appellants have stated on Page 5 that "The September 23, 1999 Office Action did not specifically mention enablement." This statement is incorrect since the action states in the next sentence that "all prior rejections of the July 29, 1998 and December 2, 1998 Office Actions had been maintained." which prior rejections included "enablement". Appellants are in error.

Appellants have argued on **Page 6**, that "every embodiment within the scope of the claims must be made available to the public" but this was not the position of this Examiner in allowing the broad process claims in the parent as well as all mutant strains of the deposited strain. This Examiner allowed much broader claims based on the limited deposited strains. Appellants have already been granted all reasonable claims commensurate in scope with the written and enabling disclosure based on the very limited deposited strain(s). The request for additional strains have been based on the

instantly claimed "mutant" strains commensurate in scope with the full claimed language that requires the additional strains in accordance with the USPTO Depository Rules.

On **page 7**, Appellants have argued "General guidance to the skilled artisan.....specification at page 6, lines 22-28, describes the basic process....." which processes as well as the strain(s) per se have already been granted in the parent applications based on "antibiotic, a cytochrome B inhibitor or a terpenoid synthetic pathway inhibitor". Appellants lack any guidance with respect to the extremely broad claimed language for one of ordinary skill in the art to make and practice the additional strains commensurate in scope with the full claimed language, other than the enabling mutant strains produced by the specific protocol indicated on page 17 and in the working examples, which inadequate written description requires the deposit of at least suitable deposit(s) that is(are) within the scope of the term"mutant"in the expression "astaxanthin mutant Phaffia rhodozyma" strain. The instant specification lacks any descriptive and enabling disclosure due to the intensity of light and in fact Appellants states on **page 11** of the instant specification, last paragraph that " The effects of light also did not effect carotengenesis of *P. rhodozyma"*. The arguments pertaining to "using a mutating agent to enhance the selection process is discussed in the specification at page 17, fourth paragraph through page 18, third paragraph. This discussion includes a list of exemplary and preferred mutagenic agents." **but the requirement** as stated on page 17 which states "....as long as antibiotic, a cytochrome B inhibitor or a terpenoid synthetic pathway **inhibitor selection is included in the protocol**." Appellants have already been granted claims to these mutagenic strains produced by the protocol selection process disclosed on page 17.

Appellants have argued on **page 10 of the Brief** that the Declaration which included sixty-seven strains having enhanced astaxanthin but all of the strains followed the above protocol as well as Experiment 5 drawn to the same protocol with respect to the selection of the mutagen by one of the above three pathways " as long as antibiotic, a cytochrome B inhibitor or a terpenoid synthetic pathway inhibitor selection is included in the protocol". For these strains, Appellants have already been granted a patent which covered the selection of irradiation mutatgens by the particular inhibitor pathway. There is absolutely no disclosure of any demonstration absent one of the above pathway inhibitors which is the position of this Examiner as to the fact that the instant specification lacks reproducibility for the claimed scope language and that Appellants had full possession of the claimed inventions . Therefore, the arguments have been deemed not to be persuasive to overcome the lack of deposits of strains in accordance with the PTO Rules of Deposits.

Appellants have argued on **Page 11**, that Appellants **should be allowed** to dominate the future patentable inventions of others **where those inventions were based in some way on his teachings** which arguments are **totally lacking in the instant application** since there is absolutely no written as well as enabling teachings or suggestions backed by any suitable working example(s) or protocol for the broad claimed language.

The arguments on pages 11-12 with respect to ***In re Fisher*** drawn to the written description have been clearly stated in the Office action as noted above:

> '...first paragraph of 35 U.S.C. 112. that paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.....In cases involving unpredictable factors, such as most chemical reactions and physiological

> activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.
> In view of the broad claimed language, the above statement:
> It is equally apparent, however, that he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. 112. that paragraph requires that the scope of the claims must bear a reasonable correlation to the ' scope of enablement provided by the specification to persons of ordinary skill in the art."

There is no reasonable correlation based on the written and enabling disclosure, that Appellants had possession of the claimed subject commensurate in scope with the full claimed language.

With respect to Fiers v. Sugano 25 USPQ2d. 1601.

> 'Applicant is absolutely not entitled to the broad claimed language for the "mutant Phaffia" which "requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity." Also, stated "We thus determined that, irrespective of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance, requires a definite of that substance other than by its functional utility."
> Applicant does not teach in the instant specification any and all mutant strains to produce pigments at a certain level but only specific mutant strains.

Appellants have argued on page 14 that the

> Declaration , Appellants have shown that by practicing the methods disclosed in the present application, numerous strains of Phaffia in accordance with the present claims are readily produced. The Declaration provides further evidence that the skilled artisan would have

> (especially after obtaining a deposited sample of wild Phaffia) been able to practice the presently claimed invention.'

which statement is true with respect to only those strains that have been taught in the specification in accordance with the protocol with a pathway inhibitor. These strains have already been patented in the parent application. The written description as well as the Declaration does not support the enablement commensurate in scope with the broad claimed inventions.

This Examiner disagrees with Appellants who have already obtained patent rights to the broadest possible claims to the processes commensurate in scope with the written as well as the enabling disclosure. Appellants have also been granted patents drawn to the all of the patented strains, see claims 1 and 3 in U.S. 5,356,809 as well as all mutants of the deposited strains see claims 2 and 4:

> 1. Phaffia strain IGI887J0.
> 2. A mutant strain of Phaffia IGI887J0 of claim 1 which produces at least 700 .mu.g of astaxanthin per gram dry weight of Phaffia per six day culture period in YM medium, wherein said astaxanthin is determined by measuring the absorbance at 474 nanometers of a petroleum ether extract of Phaffia using a 1% (w/v) extinction coefficient in a 1 centimeter cuvette of 2100.
> 3. Phaffia strain IGI887J2.
> 4. A mutant strain of Phaffia IGI887J2 of claim 3 which produces at least 700 .mu.g of astaxanthin per gram dry weight of Phaffia per six day culture period in YM medium, wherein said astaxanthin is determined by measuring the absorbance at 474 nanometers of a petroleum ether extract of Phaffia using a 1% (w/v) extinction coefficient in a 1 centimeter cuvette of 2100.

Each of the above mutant claims(claims 2 and 4) encompasses an unlimited number of mutant strains for which Appellants were not required to deposit an unlimited number of deposits since the language of the specification was sufficient to satisfy the written description. This Examiner did not require any additional strains to support the above claimed subject matter of claims 2 or 4 which claims were fully supported and enabling commensurate with the full claimed language. For the instant claims, Appellants have not conceived as well as reduced to practice 'mutant' strains of *Phaffia rhodozyma* commensurate in scope with the claimed inventions in accordance with the written description as well as the enablement requirements of 35 U.S.C. 112 first paragraph.

Part B-Adequate Written Description as noted on Pages 15-21

It is noted that the written description rejection is drawn to what was described in the specification commensurate in scope with the full scope of the 'mutant' strains for the 'mutant Phaffia rhodozyma' which would reasonably convey to one skilled in the relevant art at the time the application was filed, the inventors had possession of the claimed invention. The inventors did not convey to one skilled in the art that they had possession of full scope of strains of 'mutant ***Phaffia rhodozyma'*** but only those selected and produced by the protocol by way of pathway inhibitors. The specification does contain support for these specific pathway inhibitor mutant strains to produce more than 700 micrograms of astaxanthin per gram of dry yeast. The specification does not enable any person skilled in the art to

which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims. The specification only teaches a protocol for preparing mutants having one specific characteristic which characteristic does not lead one of ordinary skill in the art to find additional mutants by other methods without undue experimentation.

An adequate written description of the desired microorganism 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention. ***Fiers v. Revel***, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, an adequate written description of the desired microorganism requires more than a mere statement that it is part of the invention because it has a desired functional property, capable of producing at least 700 micrograms of astaxanthin, and reference to a potential method for finding it; what is required is a description of the microorganism itself. Appellants do not describe the mutant strains of ***Phaffia rhodozyma*** but only implies that the functional property of producing an amount of astaxathin which property does not meet the written description requirement for the mutant strains per se.

Whether or not the disclosure provides an enabling disclosure, it does not provide a written description of the desired microorganisms which is necessary to provide a written description of the microorganisms. The functional property is not itself a

written description of that microorganism, it conveys no distinguishing information concerning its identity, just its functional property. While the disclosure provides a process for obtaining an additional microorganisms with the claimed properties which are only produced by the pathway inhibitors, there is no further information in the application pertaining to the desired organisms characteristics; in other words, it does not describe microorganisms having the desired functional property in general. Describing a method of finding a suitable microorganism having the desired functional property, as in the example, does not necessarily describe the desired microorganism itself.

Every species in a genus need not be described in order that a genus meet the written description requirement. See ***Utter***, 845 F.2d at 998- 99, 6 USPQ2d at 1714 ("A specification may, within the meaning of § 112, first paragraph, contain a written description of a broadly claimed invention without describing all species that claim encompasses.") In claims to a specific species of microorganism from a genus, however, a generic statement such as ***Phaffia rhodozyma*** without more, is not an adequate written description of the generic microorganism because it does not distinguish the claimed species of the genus from others, except by the alleged function of enhancing the production of astaxathin. It does not specifically define any of the species of that genus that fall within its definition. It does not define any features (as commonly used in the art of microbiology) which are commonly

possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, does not suffice to define the genus because it is only an indication of what the genus does, rather than what it is. See ***Fiers***, 984 F.2d at 1169-71, 25 USPQ2d at 1605- 06. It is only a definition of a useful result rather than a definition of what achieves that result. Many such species of the genus may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See ***In re Wilder***, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

The rejected Claims are essentially of limitless breadth. It is implied that so long as the specification provides one with the ability to produce enhanced astaxanthin content which is encompassed by the material limitations, the broad claims are sufficient to meet the written description commensurate in scope with the unlimited breadth of the claimed language. The issue here

is the breadth of the claims in light of the predictability of the art. This breadth is evaluated in view of the skill level of the artisan and the only guidance presented in the instant specification involving a selection process employing pathway inhibitors to obtain the claimed mutant *Phaffia rhodozyma* strains.

The breadth of claims must be based upon the predictability of the claimed subject matter unless one has a reasonable expectation that any one material embodiment of the claimed invention would be more likely than not to function in the manner disclosed or the instant specification provides sufficient guidance to permit one to identify those embodiments which are more likely to work. As noted above, the instant specification clearly does not support the mutant strains produced by:

> An isolated pure culture of a strain of Phaffia rhodozyma which when grown under conditions comprising an oxygen transfer rate of at least 30 mmoles/l/hour on YM medium at 20. degree. - 22. degree. C. for 5 days in 500 ml shake flasks with two baffles containing 50 ml of the medium and subjected to orbital shaking at 150 rpm, produces astaxanthin in an amount of at least 600 mu.g per g Phaffia rhodozyma dry matter, as determined by HPLC analysis, wherein said strain is Phaffia rhodozyma deposited under accession No. 224-87 CBS, accession No. 225-87 CBS, or accession No. 215-88 CBS, or a mutant+ thereof which retains the astaxanthin-producing capability.

and

> Whereby -Phaffia rhodozyma strains are described which produce greater than 3,000 ppm astaxanthin based on dry yeast solids when cultivated in a volume of nutrient medium of at least about 1,500 liters and containing in excess of 4 percent, preferably in excess of 6 percent, dry yeast solids. These and other strains are cultivated by an improved fermentation method comprising extending the maturation phase of the fermentation by one or more various **techniques including exposing the yeast cells to a low-intensity light**, slow feeding the cells with a rapidly metabolized energy source, e.g. glucose, and replacing the rapidly metabolized energy source with a slowly metabolized energy source, e.g. glycerol.

In the instant case it is highly improbable that any microorganism will more likely than not perform in the manner disclosed and the instant specification does not provide the guidance needed to find other microorganisms with the desired functional property with any reasonable expectation that such microorganisms will be found.

Part C-Page 21-25

The rejections over Fleno et al 5,356,810 under 35 U.S.C. 102(b/e) have been withdrawn in view of the appropriate date of the Patent which cannot be considered to be a proper reference as correctly stated by Appellants.

D. **An Obviousness-Type Double Patenting Rejection of the Present Application over Fleno et al U.S. 5,356,810**

For Pages 26-31

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

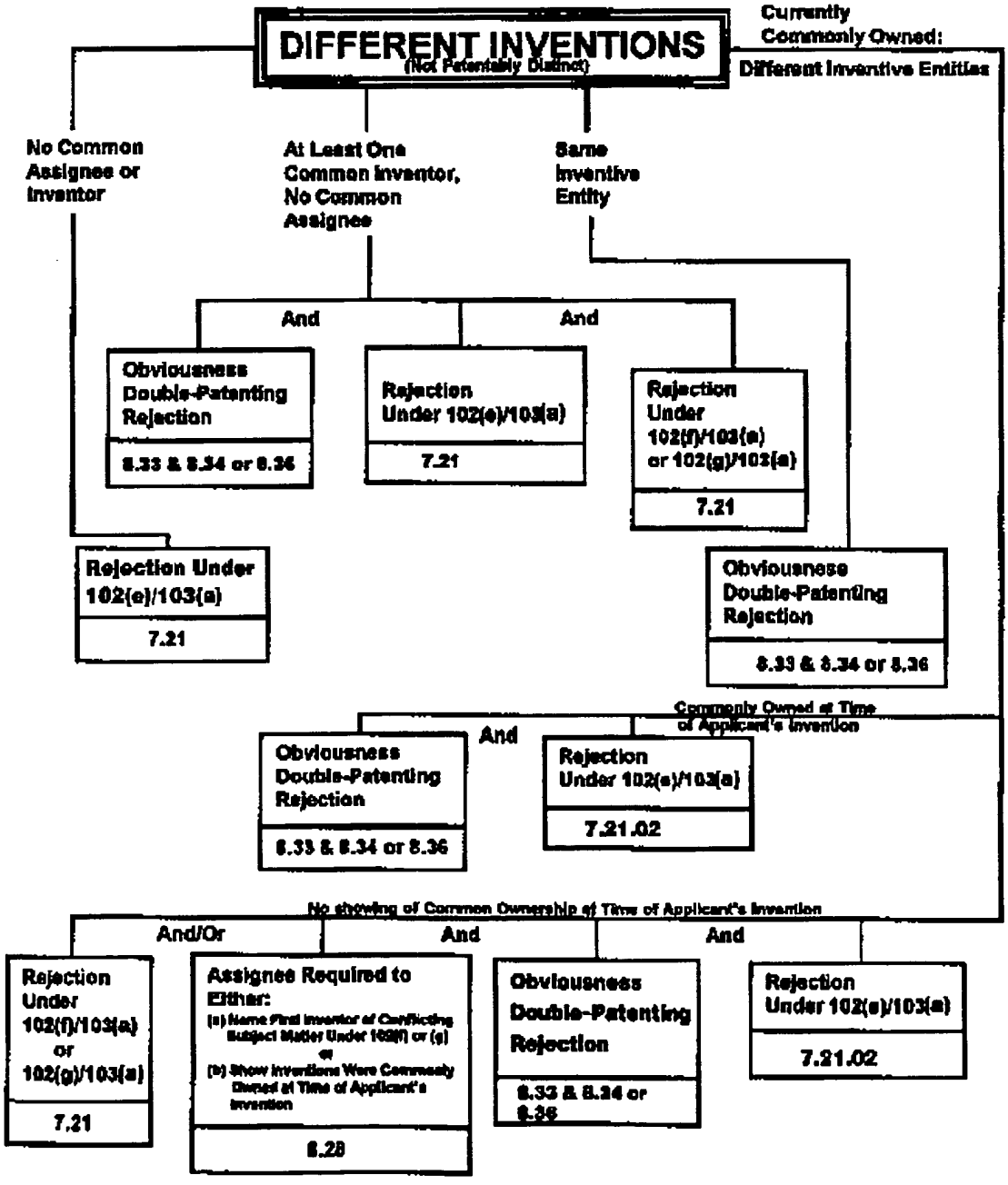
Claims are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No.5,356,810 . Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are within the scope of the patented claims, see MPEP 800-13 Chart IIB for conflicting claims between an APPLICATION AND A PATENT (copy reproduced on next page).

It is noted that Appellants are prohibited to overcome the above double patenting rejection since the two applications are not commonly owned.

> The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
>
> A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).
>
> Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

CONFLICTING CLAIMS BETWEEN: APPLICATION AND A PATENT

CHART II-B



Appellant have alleged on pages 26-28 that there were delays due to statutory art rejections based on Fleno et al, U.S. 5,356,810 and further states:

> "Because of the delays faced by Appellants, the Fleno patent which was filed subsequent to the effective filing date of the present application, issued first as a patent."

1. These allegations are erroneous based on the record that the delays prevented Appellant to obtain a patent to the instant claims prior to the Fleno patent . In the first place, the patent to Fleno et al U.S. 5,356,810 was filed on 07/27/1992, allowed on 04/26/1994 and the patent issued on 10/18/1994. It is noted that the earliest date by Appellants for the instant claimed subject matter was in a preliminary amendment filed December 23, 1993, in parent application Ser. No 08/067,797 . This Examiner had found the PCT publication to Fleno which led to the U.S. filing of 08/919,986 which was going to be allowed by another Examiner. It was this application that matured into U.S. Patent No. 5,356,810. There was absolutely no delay on the part of the Patent Office in preventing Appellants obtaining a patent since Appellants did not present the claimed subject matter prior to the Fleno patent.

2. Appellants have also argued in view of alleged delay:

> " Thus, Appellants respectfully submit that in accordance with the MPEP, at 804(II)(1)(b), a two-way obviousness analysis would be proper."

Even if there is a requirement for a two-way obviousness analysis, the sole claim of Fleno et al clearly is within the scope of the instant claims meeting all of the required limitations. The claim as recited:

> "1.An **isolated pure** culture of a **strain of Phaffia rhodozyma** which when grown **under conditions comprising** an oxygen transfer rate of at least 30 mmoles/1/hour on YM medium at 20.degree.-22.degree. C.**for 5 days in 500 ml** shake flasks with two baffles containing 50 ml of the medium and subjected to orbital shaking at 150 rpm, **produces astaxanthin** in an amount of **at least 600 .mu.g per g Phaffia rhodozyma dry matter**, as determined by HPLC analysis, wherein said strain is Phaffia rhodozyma deposited under accession No. 224-87 CBS, accession No. 225-87 CBS, or accession No. 215-88 CBS, **or a mutant thereof** which retains the astaxanthin-producing capability."

The broad instant independent claim 25 states:

> "25. An **astaxanthin mutant Phaffia rhodozyma** producing more astaxanthin than naturally occurring Phaffia rhodozyma, said **mutant producing more than 700 micrograms of astaxanthin per gram of dry yeast per six-day** culture in YM medium, wherein the amount of astaxanthin is determined by measuring the absorbance at 474 nanometers of a petroleum ether extract of Phaffia rhodozyma using a 1% (w/v) extinction coefficient in a one centimeter cuvette of 2100."

Fleno et al discloses	**Instant Claim 25**
1. An **isolated pure** ... **strain of Phaffia rhodozyma**	An **astaxanthin mutant Phaffia rhodozyma**
2. produces astaxanthin .. **at least 600 .mu.g per g rhodozyma dry matter**	**mutant producing more than 700 Phaffia microg.. of astaxanthin per g.. of dry yeast**

The expression "at least" in the claimed language "....at least 600 .mu.g per g .." in view of the specification which teaches in column 15, lines 30-37 whereby the amount of "at least" includes up to "at least 3000 ug per g of yeast dry matter." This amount of "at least" includes the required amount of astaxanthin in view of the specification, as set forth in **In re Moore**, 439 F.2d 1232, 169 USPQ 236 (1971), the definiteness of claim language must be determined by analyzing the language used in light of the supporting specification and the prior art.

3. **a mutant thereof**	...said **mutant** producing....

The additional requirement for the mutant is the amount produced for a time period:

4. **conditions comprising** ...**for 5 days in 500 ml**	**per six-day** culture

Fleno et al clearly teaches that the amount of astaxanthin produced is much greater than the instantly claimed limitation of "producing more than 600 micrograms of astaxanthin per gram" ,see Table 2, discloses the mutant strain CBS 225-87 which culture was subjected to a growth condition that produces 706 ug of astaxanthin in 5 days. In addition, Fleno et al states, as indicated above , that the amount of pigment produced is at least 3000 micrograms the various microorganisms and mutant strains in the examples, see Table 5, whereby the CBS 225-87 mutant strain for 80 hours (five days) produced 1490 micrograms which is well within the requirements of producing astaxanthin within a six day period.

The determination of the astaxanthin as required in the instant claim:

5. "...wherein the amount of astaxanthin is determined by measuring the absorbance at 474 nanometers of a petroleum ether extract of Phaffia rhodozyma using a 1% (w/v) extinction coefficient in a one centimeter cuvette of 2100."

is clearly the same measurement determination for Fleno et al as disclosed in column 13, lines 40-68.

Appellants allegations :

> "The amount of astaxanthin production of the strains claimed by Fleno 5,386,810 (600 ug) cannot be said to render the strains of the present claim, each reciting mutant strains producing at least 700 ug of astaxanthin, obvious. Indeed, the Examiner has not applied any reference to supplement the Fleno 5,356,810 reference, even suggesting ability in the art for increasing pigment production to that amount achieved by Appellants. ...Thus, the two-way obviousness determination failed to support an obviousness-type Double Patenting Rejection."

that Fleno et al reference does not meet the claimed limitations are totally erroneous, inaccurate and groundless in view of the disclosure of Fleno et al as noted above. The growth conditions of Fleno et al for the mutants per se are clearly greater than the required 700 micrograms which clearly supported that the obviousness double patenting type rejection is proper.

With regards to the remarks on pages 29-31, this Examiner followed the guidelines as outlined in the MPEP 804 at IIB based on the Obvious-type Double Patenting Rejection which guidelines required the rejection.

For the above reasons, it is believed that at least (a), (b) and (c) rejections should be sustained.

Respectfully submitted,

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